OCT - 6 2000

PARADIGM MEDICAL INDUSTRIES INC.,
2355 South 1070 West
Salt Lake City, Utah 84119
(801) 977-8970
(801) 977-8973 (fax)
Tracy S. Best, Manager of Regulatory Affairs
Preparation Date: July 21, 2000

K002228

Summary of Safety and Effectiveness for the:

Trade Name: Photon Workstation w/532 module

Common Name: Solid State Diode, Frequency Doubled, 532 nm

Classification Name: Ophthalmic Photocoagulator

Legally Marketed Predicate Devices for Substantial Equivalence:

* Spectrum Veinlase, Manufactured by Instruments for Medicine and Surgery

* Elite Laser, Manufactured by FISMA, Inc.

Rationale for SE: The Spectrum Veinlase and the Elite Laser and Delivery Devices share similar indications for use in ophthalmology, similar design features including; wavelengths, beam integrity, and cooling type. Control systems such as interlock devices, (safety systems) and displays are constantly monitored for user intervention. Functional features such as; delivery power, pulse rates, energy type, and spot sizes are also similar to the aforementioned devices. *Also see Attachment "A"* Comparison Chart of Equivalence.

Description of Submitted Device:

The Photon Modular Workstation W/Laser System is an instrument for use in the application of Ophthalmology. The addition of a pre-approved (currently marketed), fully contained laser module, to be controlled by the Photon is the basis of this submission. The laser light is produced by Solid State technology. With a output power of up to 3 Watts using 532 nm green light, additional indications for use are warranted. Indications for use are supported by readily available (OEM) SMA Connector Type fiber optic delivery devices. They include endoprobes, bent and straight of different gauges fiber, as well as slit lamp adaptors for the delivery of laser energy through a slit lamp.

Intended Uses of the Elite Family Lasers:

See attachment "B" for a complete listing of indicated uses.

Technological Characteristics and Substantial Equivalence:

The Spectrum Veinlase primary energy output source is an arc lamp excited YAG rod that produces infrared laser light that my be delivered to the patient or for purposes of this submission, frequency doubled to 532 nm green for the delivery to the patient and treatment. This system has various timing features for interval, and duration. The Aiming Beam has a Visible Red Diode @ 630-680 nm wavelength.

The Elite Laser System uses an infrared (808 nm) semiconductor diode laser light as the primary source of energy and is then converted to a visible wavelength of 532 nm laser light. The Elite Laser System delivers the same wavelength, similar power, spot sizes and pulses of equivalent duration to the purposed Photon Platform Workstation W/532 laser.

Nonclinical Performance Data

None

Clinical Performance Data

None

Conclusion:

The Photon Modular Workstation W/532 Laser System is substantially equivalent to other existing surgical laser systems in commercial distribution. The Photon concept is built on the already approved Precisionist Thirty Thousand ref: K953447. The laser module is an OEM laser that is integrated into and enclosed in the Photon (Ocular Surgical) System. The laser has internal software that communicates with the Photon and accept commands. This allows the flexibility for physicians to add modules to already purchased capitol equipment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 2000

Ms. Tracy S. Best
Manager, Regulatory Affairs
Paradigm Medical Industries, Inc.
2355 South 1070 West
Salt Lake City, Utah 84119

Re: K002228
Trade Name: Photon Modular Workstation System
Regulatory Class: II
Product Code: GEX
Dated: July 21, 2000
Received: July 24, 2000

Dear Ms. Best:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002228

Device Name: Photon Modular Workstation System

Indications For Use:

Ophthalmology:
- Retinal Photocoagulation
- Trabeculoplasty
- Iridotomy
- Peripheral Iridectomy
- Diabetic Retinopathy
- Posterior and Anterior Procedures
- Other conditions of the retina in which the laser is deemed useful involving endophotocoagulation
- Extra-orbital pigmented or venous lesions including;
  - Telangiectasia
  - Treatment of Chronic Dacryocystitis

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Melkerson

(Division Sign-Off)

Division of General Restorative Devices

(510(k) Number K002228

Prescription Use X **OR** Over-The-Counter Use _____

(Per 21 CFR 801.109)